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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,728	11/01/2001	Cohava Gelber	3828-4001US1	7840

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,728	GELBER, COHAVA	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Claims 50-57 are pending and under consideration. All objection and rejections set forth in the previous Office action is moot because the claims are cancelled. Any rejection of record not applied to the new claims is withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 50-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As stated in the previous Office action mailed on 12/28/2004, this rejection has two parts.

Applicant argues that the submitted receipt from ATCC showing the claimed hybridoma cell lines secreting the claimed monoclonal antibodies have been deposited under Budapest Treaty and the amendment to the specification would obviate the enablement rejection. This argument along with the evidence (i.e. the biological statement from ATCC, Exhibit 1) has been fully considered but the enablement rejection of record is applied to the new claims because an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following

criteria have been met: All restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

The second part of rejection has to do with the preamble "pharmaceutical" in claims 53.

Applicant argues that the case law, for example In re Bundv, 642 F.2d 430, 209 USPQ 48 (CCPA 1981) clearly distinguishes between claims drawn to a compound and claims drawn to the therapeutic use of the compound, the latter requiring a greater burden. However, the law does not distinguish between claims drawn to a compound and claims drawn to a pharmaceutical composition comprising the compound. The only relevant question is whether the claim recites a therapeutic use. The present claims do not recite a therapeutic use. Applicant cites MPEP 2164(c), and Raytheon Company v. Roper Corporation (CA FC) 220 USPQ 592 (12/30/1983) in order to make a point that a claimed invention need not accomplish all objective stated in the specification in order to satisfy the enablement requirement. Applicant argues that since claim 53 is not limited to pharmaceutical for SCLC treatment, and use in vivo administration to localize and/or image SCLC cells and produce anti-idiotypic antibody are contemplated as possible uses for the claimed pharmaceutical, the disclosure satisfy how to use requirement of 35 U.S.C. section 112, first paragraph.

These arguments have been fully considered but found unpersuasive for the following reasons. In re Bundy decision has to do with how to use an analog of a well-known compound, prostaglandin. The claim in In re Bundy did not recite "pharmaceutical" as in the instant case. The court said that it does not cause undue

experimentation to use an analog of a known compound, i.e. prostaglandins even if the specification did not spell out the necessary dosages for in vivo biological uses. In summary, In re Bundy decision is not applicable to the instant claim because the claimed pharmaceutical comprising an antibody is a novel product without any known analog that one of skill in the art had been using before the effective filing date of the instant application. As for argument with MPEP 2164(c), and Raytheon Company v. Roper Corporation, both MPEP 2164(c), and Raytheon Company v. Roper Corporation are also about one of ordinary skill would be able to figure out how to use a variation of a known product, an household oven in the case of Raytheon Company v. Roper Corporation even if the disclosure does not spell out how to use the claimed variation of a well known product. Here, the main ingredient in the claimed pharmaceutical is an antibody without any known analog. One of skill in the art would not know how to use the novel antibody as in vivo diagnostics. The Office agrees with applicant that administration of the muse monoclonal antibodies to host another than mouse (for example human) would generate an anti-idiotypic antibody because the antibody being administered is a foreign and thus an antigen. However, the specification does not teach who needs such anti-idiotypic antibody by in vivo administration of the claimed pharmaceutical. As in the case of In re Bundy, one of skill had known how to use prostaglandins in vivo before the effective filing date of the patent application resulted in In re Bundy, thus the court said one of the skill in the art would be able to figure out the does for the claimed analog in the similar biological effects as other prostatglandins. As in the case of Raytheon Company v. Roper Corporation, almost

anyone would be able use an oven. However, the instantly claimed pharmaceutical does not have any analog, therefore the burden for enablement is higher. The specification does not disclose which disease would be treated by generating an anti-idiotypic antibody to the claimed pharmaceutical. The specification does not teach how to use the claimed pharmaceutical as a diagnostic agent. As applicant notes, the claimed pharmaceutical comprising the antibody would generate an anti-idiotypic antibody, which will binds to the administered antibody for in vivo imaging, thus preventing to reach the site desired. Since the claimed pharmaceutical does not have any equivalent product, one of skill would does not have any reference point to guide one of skill to use the claimed pharmaceutical other than resorting to an undue experimentation to figure out what is the right dosage in order to overcome the effect of anti-idiotypic antibody complex formation for in vivo diagnostic usage.

Considering the unpredictable state of art, limited guidance, no examples in the specification how to use the instantly claimed pharmaceutical, it is concluded that undue experimentation is required to practice the invention.

Claim Rejections - 35 USC § 102

Claims 51, 53-55, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Rose et al., of record, cited in the previous Office action (#3 IDS filed on 12/02/2004, Hybridoma vol. 13, pages 221-227).

Claims 51, 53-55, and 57 are interpreted as drawn to hybridoma and a monoclonal antibody, which binds to an antigen competitively inhibits a second monoclonal antibody of Moab 51.2, 37.14, 109.12, or 26.1, wherein the antibody is

labeled with a detectable moiety (claim 54), and wherein said detectable moiety is a label commonly used in the art for detection (claim 55), while the antigen recognized by the instantly claimed antibody is slightly less than 98 kDa.

Applicant argues that the antigen recognized by CR101 of Rose is a highly glycosylated cell surface antigen associated with SCLC that resolves into two proteins of 94 and 115 kDa by SDS- PAGE while the antigen recognized by the antibodies of the present invention when deglycosylated is a single protein of slightly less than 98 kDa resolved by SDS-PAGE as shown by Krueger of record.

These arguments have been fully considered but found unpersuasive because CR101 monoclonal antibody appears to bind the same antigen, i.e. expressed on the surface of SCLC, and antigen of about 200 kDa when glycosylated, slightly less than 98 kDa when unglycosylated. Note the size comparison between Fig. 2 of Kruger vs. Rose et al at shown at Fig. 4, as well as Fig. 7, and Table 2), where the antigen is characterized to be about 200 kDa as determined by SDS-PAGE (note Fig. 4) when glycosylated (note Table 1), but slightly less than 98 kDa when deglycosylaed.

As stated before in the previous Office action, the Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the antibody, hybridoma, pharmaceutical composition of the prior art does not possess the same material, structural and functional characteristics of the instantly antibody, hybridoma, pharmaceutical composition. In the absence of the primary structure(s) of the antigen(s) the instantly claimed invention binds to, characteristic of the antigen of the prior art and the claimed antibody are same, it is the Office's position that they are

the same. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed composition is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 103

Claims 51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al., (#3 IDS filed on 12/02/2004, Hybridoma vol. 13, pages 221-227) in view of Ward, ES (1992, Antibody Engineering, W. H. Freeman and Company, Car. A. K. Borrebaeck, ed, pages 122-123 only).

Claims 51, and 52 are interpreted as drawn to a Fab fragment made from the antibody of the base claim 51 (see the interpretation of claim 51 above).

Applicant argues that the claimed invention does not encompasses the antibody of Rose et al. However, applicant does not provide any evidence that the claimed invention is different from Rose et al. As stated above, both antibodies bind to the same antigen, i.e. expressed on surface of SCLC, about 200 kDa when glycosylated, but slightly less than 98 kDa when deglycosylated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642